DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 23, 2014

Liaoning Kampo Medical System Co., Ltd.
% Mr. Shao Kai
Quality Engineer
No. 9, Yaodu Street, Benxi Economic Development Area
Benxi, Liaoning 117004
CHINA

Re: K131737
Trade/Device Name: Supernova C5 MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: July 19, 2013
Received: September 25, 2013

Dear Mr. Kai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131737

Device Name
Supernova C5 MRI System

Indications for Use *(Describe)*
The Supernova C5 is intended for use as a diagnostic imaging device which can produce transverse, sagittal, coronal and oblique cross-sectional images of the internal structure of the human head, body or extremities.
The images produced by MRI system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510（k）Summary

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92

1.0 Contact Information

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2.0 Establishment Name and Address

Liaoning Kampo Medical System Co.,Ltd.
No.9, Yaodu Street, Benxi Economic Development Area,Liaoning,P.R.China
Post Code : 117004

3.0 Submission Date

May 31, 2013,revised September 19,2014

4.0 Device Information

Trade Name:	Supernova C5 MRI System
Product Model:	Supernova C5
Classification name:	21 CFR Part 892.1000 Magnetic resonance diagnostic device
Product Code:	LNH
Device Class:	Class II

5.0 Predicate Device(s)

510(k)#	Device	Original Applicant	Decision Date
K071154	Superstar 0.35T	NEUSOFT MEDICAL SYSTEMS CO., LTD	05/10/2007

6.0 Device Description

The Supernova C5 is a 0.35T permanent magnet MRI system. It is composed of Magnet and Magnet Enclosure, RF Coils , Patient Couch, System Cabinet, computer system. The system software based on Windows XP or Windows 7 is an interactive program with user-friendly interface. Its functions cover scanning control, image reconstruction and image/archive management and maintenance.

Supernova C5 has been designed to comply with the FDA Recognized Consensus Standards listed in the table below, as applicable to device features and components:

Reference #	Title
IEC60601-1	Medical electrical equipment - Part 1: General Requirements for Safety
IEC60601-2-33	Medical electrical equipment--Part 1:General requirements for safety-2. Collateral Standard: Electromagnetic compatibility—Requirements and tests
MS 1-2008	Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnet Resonance Imaging
MS 2-2008	Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images.
MS3-2008	Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
MS4-2010	Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices
MS5-2010	Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging.
MS6-2008	Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel, Non-Volume Coils in Diagnostic Magnetic Resonance Imaging (MRI)
MS8-2008	Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
MS9-2008	Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI)
NEMA PS3.1 - 3.20 (2011)	Digital Imaging And Communications In Medicine (DICOM) Set.

7.0 Indications for Use

The Supernova C5 is intended for use as a diagnostic imaging device which can produce transverse, sagittal, coronal and oblique cross-sectional images of the internal structure of the human head, body or extremities.
The images produced by MRI system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination

8.0 Technological Characteristics Comparison to Predicate Device

The Supernova C5 is comprised of the following functional modules, and the predicate device contains the same functional modules:

- Magnet – responsible for providing a homogeneity magnetic field in specified space.
- Gradient Coil – generates a linear gradient field in specified space when excited by electric current.
- Gradient Amplifier – provides high electric current for gradient coil
- Transmit Coil – generate a homogeneity RF field in specified space when driven by RF power
- RF Amplifier - provides RF power for transmit coil
- RX Coils – receives the FID signal which has excited by the transmit coil and encoded by the gradient coil.
- Spectrometer – receives parameters transferred from scan control to generate time sequence to control the operation of gradient amplifier, RF amplifier and RX coil. The signal from RX coil will be digitized and transferred to SW for further processing
- User Interface (SW) - user can get desired images by proper operation in UI.
  - Acquisition - Receive MR raw data from spectrometer
  - Reconstruction - responsible for the efficient processing of raw data to generate MR images.
  - Analysis - contains the image post-processing tools
  - Protocols - Supernova C5's each protocol is comprised at a pulse sequence, user parameters.
  - Scan Control - responsible for the real-time transfer of controlling orders for protocols, protocols parameters modifications, and dynamic information from the MR host in response to user or program requests

- Information System - the central repository of all relevant MRI system configuration, patient, study, scan, etc., parameters associated with the current patient study
- Storage - obtains current patient and scan information, performs non-volatile local storage, exports images and data in DICOM format.
- Visualization - implements all aspects of the user interface, including scan protocols selection, controls to modify protocol parameters, image display, graphical slice prescription, and image review, save, and export.

- Patient couch – provides a support for patient during scanning.
- Cover – provides a shell for magnet

There is no differences between the Supernova C5 and the predicate device's intended use.

Both Supernova C5 and the predicate device can offer pulse sequences. Supernova C5 are optimized for whole body applications, and offer the imaging capabilities same as predicate device.

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

9.0 Performance Data – Discussion of Non-Clinical Tests

Design controls quality assurance measures during the development of Supernova C5 include:

- Customer requirement analyze
- System requirement analyze
- Detail design
- Design reviews
- Unit and integration level testing
- Verification testing, including System and Manual testing
- Safety testing, including SAR, dB/dt, and acoustic noise
- Performance testing, including SNR and uniformity
- Validation testing

Risk management, compliant with ISO 14971:2007, identified hazards, sequences of events, and resultant harms: developed, implemented, and tested risk-controlling mitigations: and evaluated residual risks.

10.0 Safety Parameters

	Supernova C5	Predicate Device
Magnet field strength	0.35T	0.35T
Operating Modes IEC 60601-2-33 (2010-03)	Normal Level Operating Mode	1st Level Operating Mode
Safety Parameter Display	SAR, dB/dt	SAR, dB/dt
Max SAR	<2W/kg whole-body	<2W/kg whole-body
Max dB/dt	Normal Level Operating Mode	1st Level Operating Mode

11.0 Performance Data - Discussion of Clinical Tests

Sample clinical images were obtained for all receive coils and pulse sequences included with the system.

12.0 Conclusions

The conclusions drawn from the nonclinical and clinical tests that demonstrate that Supernova C5 is as safe, as effective, and performs as well as the predicate device.